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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,569	05/25/2001	Anthony E. Bolton	033136-185	4479

7590

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/866,569

Applicant(s)

BOLTON ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8, 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. The amendment filed 8/26/2002 (paper no. 11) is acknowledged and entered into the record.
2. Claims 1-15 have been canceled without prejudice, claims 16-28 have been newly added. Therefore, claims 16-28 are pending and examined on the record.

#### ***Information Disclosure Statement***

3. The Information Disclosure Statements filed 6/10/2002 & 8/26/2002 (paper no. 8 & 12) are acknowledged and considered. A signed copy of the IDS is attached hereto.

#### ***Double Patenting – Maintained***

4. The provisional rejection of claims 3-14, of which are canceled and replaced with claims 17-27, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-14 of copending US Application No. 09/866,488 is **maintained**, for the reasons of record. Applicant argues that although the method steps are similar and are recited in the same manner, the scope of the claims are directed to patentably distinct subject matter. Applicants arguments have been carefully considered and are not found persuasive for the following reason. It is known in the art that the mechanism of action associated with the administration of apoptotic bodies is through the immune system's activation of inflammatory cells, such as macrophages or APC (see Henry *et al*). It is also known that apoptotic bodies are able to adhere to endothelial cell (as taught in light of Dini *et al* (J Cell Sci. 1995; 108:967-973)). Therefore, although claimed in different ways, the scope of the invention encompasses

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the same treatment of disease, because a T-cell or inflammatory disorder is treated in both applications.

***Claim Rejections Maintained-35 USC § 102 (b)***

5. The rejection of claims 1, 2, and 15 of which are canceled and replaced with newly added claim 16 under 25 USC 102(b) is ***maintained***, for the reasons of record. Applicant argues that the Henry reference does not specifically recite all of the limitation set forth in the instant claims, wherein the claims as currently directed to a method of treatment or prophylaxis for medical diseases resulting from endothelial dysfunction. Furthermore, applicant argues that the Henry reference does not specifically recite any of the diseases named in the claims. Applicant's response has been carefully considered, but is not found persuasive for the following reasons. The claims, as currently interpreted, are not drawn to a method of treatment or prophylaxis for medical disease resulting from endothelial dysfunction, but are rather drawn to a method of treatment or prophylaxis of medical disorders (selected from the list provided in claim 16) OR involving endothelial dysfunction. Therefore, the treatment or prophylaxis is directed to two types of conditions, namely medical disorders and endothelial dysfunctions. Cancers, as well disclosed in art, results from the uncontrolled or "dysfunctional" growth of endothelial cells, wherein the uncontrolled or "dysfunctional" growth results from unwanted or undesired angiogenesis. Such uncontrolled growth can be interpreted as an endothelial "dysfunction". The Henry reference clearly teaches the claim as currently interpreted because Henry *et al* teach that the administration of

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apoptotic bodies to a mammalian patientmouse resulted in the treatment of cancer.

Therefore the rejection of claim 16 is maintained.

***Claim Rejections Maintained – 35 USC § 103(a)***

6. The rejection of claims 3-5, 12-14 of which are now canceled and replaced with claims 17-19, 21, and 25-27 under 35 USC 103(a) is ***maintained*** for the reasons of record. Applicant argues that the Henry reference is in error because the reference does not teach or suggest all the claim limitations. Applicant further argues that one of skill in the art would not be motivated to use the teachings of Henry *et al* to treat the specifically named disorders and that because such disorders are not mentioned in the reference and because of the newly amended claim, the instant rejection is rendered moot. Applicant's arguments have been carefully considered and are not found persuasive for the reasons set forth, *supra*, and for the following reasons. As described above, (see Claim Rejections Maintained – 35 USC 102(b)) the Henry reference teaches that the use of apoptotic bodies for the treatment of cancer, a disease associated with endothelial dysfunction. Although the specific limitations set forth in the instant invention are not taught by Henry *et al*, the form, dosage, and types of cell administered to the mammalian patient is routine experimentation and part of the optimization of in vivo administration. Furthermore, one of ordinary skill in the art would recognize that such a method would be useful for the treatment or prophylaxis of endothelial dysfunction because one of skill in the art would know that cancer is associated with endothelial dysfunction. One of ordinary skill would be motivated to

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apply the teachings of Henry to other disease because the method has been demonstrated as being successful.

***Claim Rejections Withdrawn***

7. The rejection of claims 1-8, 12-15 under 35 USC 112, 2<sup>nd</sup> paragraph for being indefinite, is **withdrawn** in view of the amendment to newly added claims and in view of the cancellation of claims

8. The rejection of claims 1-14 under 35 USC 112, 2<sup>nd</sup> paragraph and 35 USC 101 for lacking steps in the method/process is **withdrawn** in view of the cancellation and amendments to the newly added claims.

***Claim Objections Withdrawn***

9. The objection of claim 1 as being substantially similar to claim 15 is withdrawn in light of the cancellation of both claims 1 and 15.

***Conclusion***

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Christopher Yaen  
Art Unit 1642  
November 17, 2002



ALI R. SALIMI  
PRIMARY EXAMINER